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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/833,637      | 04/13/2001  | Yoshikatsu Kodama    | 011900-309          | 3072             |

7590

10/22/2002

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 10/22/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/833,637

Applicant(s)

KODAMA ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/3/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-30 is/are allowed.
- 6) ☒ Claim(s) 16-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                              |                                                                             |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. Applicants indicate the submission of English translation of Japanese Application 2000-113913, not 2000-113912 is acknowledged. A certified copy of Japanese Application 2000-113913 has been provided, which is indicated by the receipt of the certified copy, however, it is not in the file. Please provide a photocopy of the priority document.

#### ***Status of the Claims***

2. Claims 12-30 are pending.

Applicants' amendment filed on July 03, 2002 (Paper No. 8) is acknowledged, and applicants' response has been fully considered. Claims 16, 17 and 27-30 have been amended, claims 12-15 stand withdrawn from consideration, and claims 16-30 are under examination.

#### **Rejection Withdrawn**

##### ***Claim Rejections - Obviousness Type Double Patenting***

3. The previous rejection of claims 16-20 and 22-26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U. S. Patent 6,235,709, is withdrawn in view of applicants' submission of terminal disclaimer in Paper No. 7.

##### ***Claim Rejections - 35 USC § 112***

4. The previous rejection of claim 25, under 35 U.S.C.112, second paragraph, regarding "an inhibitor of gastric secretion" or "a method which utilizes specific adsorption to *Helicobacter pylori* urease", is withdrawn in view of applicants' response at pages 4-5 in Paper No. 8.

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is indefinite because of the use of the term "An inhibitor of *Helicobacter pylori* colonization, comprising as an active ingredient the glycoprotein". The term "An inhibitor of *Helicobacter pylori* colonization, comprising as an active ingredient the glycoprotein" renders the claim indefinite, it is unclear whether the inhibitor of *Helicobacter pylori* colonization is the glycoprotein or a composition comprising the glycoprotein.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 16 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson *et al.* (U. S. Patent 5,505,955).

Peterson *et al.* teach a glycoprotein, which has a molecular weight of 46 kDa and is isolated upon fractionation of human milk fat globules (column 5, lines 23-35; Example 7), absent factual data to the contrary, is the claimed glycoprotein and has the inherent property of the claimed glycoprotein (claim 16). Therefore, chicken egg or milk is anticipated as a food (claim 24) and a pharmaceutical composition (claim 23) which have the property of the glycoprotein, and as an inhibitor of *Helicobacter pylori* colonization (claim 22). Chick egg or milk also contains fat which is an inhibitor of gastric acid secretion, therefore chicken egg or

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milk is anticipated as an inhibitor composition of *Helicobacter pylori* colonization (claim 25) and a pharmaceutical composition (claim 26) which contain the properties of the glycoprotein and fat.

7. Claims 17-21 are rejected because they are dependent from a rejected claim.

***Conclusion***

8. Claims 16-26 are rejected, it appears claims 27-30 are free of prior art and allowable.

***Art of Record***

Chick egg or milk contains the glycoprotein which binds to urease of *Helicobacter pylori*, inhibits the adherence of urease to gastric mucosa, and eliminate colonized *Helicobacter pylori* in the stomach because the specification indicates the glycoprotein is obtained from milk of a cow or albumen of a chicken egg (page 3, line 25-page 4, line 6). Hashimoto *et al.* (Digestive Disease and Sciences, 36, 888-892 (1991) teach fat is an inhibitor of gastric acid secretion (page 889, right column; page 890, left column; Fig 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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October 2, 2002

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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October 18, 2002